Seventy-First Meeting of the

Obstetrics and Gynecology Devices Panel

Tuesday, March 28, 2006
Gaithersburg Hilton, Gaithersburg, MD

General Topic Discussion – Pivotal Studies to Evaluate New Treatment Modalities for Symptomatic Uterine Fibroids

DRAFT Discussion Questions

Pivotal Studies to Evaluate New Treatment Modalities for Symptomatic Uterine Fibroids

Over the years, CDRH has evaluated many different devices and device systems for treating symptomatic uterine fibroids. Some of these devices have already undergone clinical trials and been either cleared for use via 510(k) or approved via PMA. There are others "in the pipeline." These studies pose real challenges in terms of practical design and clinical significance. Therefore, we are requesting your input on the following key issues:

1. The primary symptom of problematic fibroids is bleeding. Other symptoms include pain, urinary problems, infertility, bulk symptoms, etc. Please discuss what you believe to be the most appropriate parameter to use in the evaluation of device effectiveness (e.g., bleeding score self-report, measurement of fibroid size (or perfusion) after surgery, quality-of-life instruments, other).

2. Based on your response to the previous question, please comment on any specific inclusion and/or exclusion criteria which should be made part of the eligibility criteria for subject enrollment, including minimum or appropriate baseline scores, measurements or symptom level."

3. For each of the important outcome measures, please discuss what the acceptable definition of individual patient success would be post-treatment and when that measurement should be assessed.

4. Selection of an appropriate control arm for surgical procedures can be challenging. In the past, the panel has criticized a non-randomized control group of hysterectomy patients. For some procedures, a sham control is not possible. Discuss other possible control options, e.g., myomectomy vs. no control (i.e., patient serving as her own control). What is the role of randomization?

5. For the various study design possibilities, please discuss the definition of study success, i.e., how good is good enough. Please specifically comment on what would be the minimally accepted percentage of treated patients who meet the individual patient success criteria discussed previously, to define the study as an overall success. In the case of a controlled study, comment on whether there is a minimum difference between the percentage of successful patients in each arm that would be needed for the study to be called a success.

6. FDA has typically asked manufacturers to provide premarket evidence of treatment success at the 6-month point after surgery, with the understanding that study subjects will be followed for a minimum of three years. Please discuss the appropriateness of this premarket/postmarket balance. Does it depend on the outcome measure itself?